K100604 #1/4

510(k) SUMMARY

As required by section 807.92

JUN 14 2010

1. GENERAL INFORMATION

Type of 510(k)	TRADITIONAL
Trade Name	OTIS-C Plus
CFR section	21CFR 888.3030
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Device panel	ORTHOPEDIC
Product Code	HRS: PLATE, FIXATION, BONE HWC : SCREW, FIXATION, BONE
Class	II
Legally marketed predicate devices	K041709 NUMELOCK II SYSTEM manufactured by HOWMEDICA OSTEONICS CORP (now STRYKER ORTHOPAEDICS) and K973812 ARTHREX PUDDU OSTEOTOMY SYSTEM manufactured by ARTHREX, INC.
Submitter	SCIENCE FOR BIOMATERIALS Sciences et Bio Matériaux ZI du Monge F 65100 LOURDES – FRANCE Registration Number : 3004549189
Contact	Denis CLEMENT, CEO Tel : +33 (0)5 62 42 21 01 Fax : +33 (0)5 62 42 21 00 e-mail : denis.clement@sbm-fr.com Regulatory contact: Idée Consulting (FRANCE) Isabelle DRUBAIX e-mail : idrubaix@nordnet.fr

2. DEVICE DESCRIPTION

The OTIS-C Plus plate is designed for the stabilization of High Tibial Osteotomy with a medial approach. Anatomically shaped, thin and short, the OTIS-C Plus plate enables mini-invasive surgery. Its locking system provides immediate compression of the graft as well as stable fixation, thus allowing early weight-bearing. The design of the self-tapping OTIS-C Plus screws allows easy and reliable one step locking, without counter-nut, in a simple and concise approach. With its range of twelve screws lengths, fixation can be either mono or bi-cortical, upon the choice of the surgeon.

3. INDICATIONS FOR USE

OTIS-C Plus is intended to be used in conjunction with bone screws to provide fixation following Proximal Tibial opening wedge osteotomies.

4. SUBSTANTIAL EQUIVALENCE

Both OTIS-C Plus system and its predicates are plate and screw systems made of stainless steel. Plates included in all these systems present 4 holes. Both OTIS-C Plus system and its predicate NUMELOCK II SYSTEM include screw 6.5 mm in diameter and plate 3 mm thick. Both plates and screws are supplied in a similar range of length.
Non clinical performance testing including fretting corrosion, and determination of torsional yield strength, ultimate, insertion and removal torque and Pull-out strength demonstrate that OTIS-C Plus system is as safe, as effective, and performs at least as safely and effectively as its predicate devices.

Summary preparation date: revised May 31, 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Science Et Bio Materiaux (SMB)
% Mr. Denis Clement
Zi du Monge
Lourdes
France 65100

JUN 14 2010

Re: K100604
Trade/Device Name: OTIS-C Plus
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: June 01, 2010
Received: June 03, 2010

Dear Mr. Clement:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K100604

Device Name: OTIS-C Plus

Indications for Use:

OTIS-C Plus is intended to be used in conjunction with bone screws to provide fixation following Proximal Tibial Opening wedge osteotomies.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100604